

Last updated Thursday, April 9, 2020 at 9:30 a.m.

Click [here](#) for a pdf version of these FAQs.

Please also see:

- Information from the CTSI: <http://www.bu.edu/ctsi/covid-19-guidance/>
- Information from BU: <https://www.bu.edu/covid-19-information/>
- Information from BMC: <https://www.bmc.org/covid-19>
- Information from FDA: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trials>
- Information from NIH: https://grants.nih.gov/grants/natural_disasters/corona-virus.htm
- The Zoho Discussion Group for Clinical Research Professionals:
<http://www.bumc.bu.edu/crro/research-professional-network/resources-programs/q-a-forum/>

Or contact medirb@bu.edu with any additional questions.

1. What types of disruptions to research are occurring now?

On Thursday, March 12, 2020, the Institutional Officials at Boston University Medical Campus and Boston Medical Center determined that most research activities involving in-person interactions with subjects **MUST STOP** until further notice. The only exceptions are if canceling or postponing the activities would either (A) increase the risk to the subject's safety or wellbeing or (B) deprive the subject of a potential direct benefit. This is being done to protect research subjects. Please see the IRB [home page](#) for the complete announcement.

2. What does this pause mean for interactions with enrolled subjects in the Boston area?

Most research activities that involve face-to-face interaction with subjects at BMC or the BU Medical Campus must stop.

The exceptions are:

- 1) The research holds the potential for direct benefit to the subject (e.g., investigational drug, devices or surgical procedure) and the interaction is required to deliver that potential direct benefit
- 2) Collection of safety data (based on clinical judgment of the importance of the visit to detect potential adverse events)

Research on the Charles River Campus should follow the BU guidelines: [BU CRC IRB Statement on Research Concerns of COVID-19 \(Coronavirus\)](#)

3. What does this pause mean for interactions with enrolled subjects outside the Boston area? (EDITED 3/24/20)

The decision to pause most face-to-face activities was based on the situation in Boston and the need to free up resources at BMC and protect research subjects and staff. The Principal Investigators of studies in other locations should use their judgment (and the judgment of colleagues) to determine the most prudent approach for studies outside of Boston. IRB permission is not needed to either continue or pause study activities.

4. What does this pause mean for research activities that involve no face-to-face interactions?

Research activities that involve no face-to-face interactions with subjects may continue.

5. Should enrollment be halted right now? (UPDATED 3/30/20)

Yes. The only exceptions would be studies where there is no in-person subject contact (e.g., on-line only) and studies with the potential for direct benefit, that is, benefits that are not available through standard of care. Existing studies that would like to convert to a remote consent process should submit an amendment to use a modified signature page (see #23 below). See also #16 below for how to this halt in enrollment affects recruitment activities.

6. What is the effect of the pause on pending studies?

The IRB will continue to review and approve submissions. For studies that are approvable, but involve in-person interactions with study subjects and do not have the potential for direct benefit, the IRB will approve the study but explicitly note that enrollment cannot start until the pause in clinical research activities is lifted.

7. What types of additional disruptions to research may occur in the future? (EDITED 3/24/20)

The Principal Investigator of studies that are not paused should develop a plan to continue study activities that are essential to subject safety and well being in the face of significant staffing shortages, being unable to obtain study drugs or protective equipment, or further limits on the availability of BMC clinical services and space.

8. What is the most important consideration in responding to research disruptions?

It is the responsibility of the Principal Investigator to identify any research procedures that would be essential to continue for the safety and well-being of the subjects, and to develop a plan to continue to deliver these procedures and monitor for safety even in the face of disruptions.

9. What else is important to plan for?

Principal Investigators must identify procedures that are not essential to subject safety but that are important to the integrity of the study data, and determine whether there are alternative methods to mitigate the loss of data, such as remote contact by phone or secure email.

10. What steps will assist in minimizing the impact of potential future disruptions? (EDITED 3/24/20)

Principal Investigators should ensure study files are shared to a secure cloud-based storage (for BMC [Box.com](#), for BU, various [cloud services](#)) and ensure that research staff have secure remote access. Principal Investigators should also have a plan for communicating among study staff, including handing off responsibilities from staff who are ill.

11. Do research subjects need to be screened for COVID-19?

Please consult the [latest guidance](#) for screening patients at BMC

12. How do subjects need to be notified of visit cancellations and changes?

When a study visit needs to be cancelled or changed to a phone call or on-line encounter, the subject should be told the reason and that they will be contacted again when the visit can be rescheduled. These messages to subjects do not require IRB approval. BMC Research Operations and the IRB have created the following Subject Communication template that you may use and modify as needed:

<http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-subject-letter-template.docx>

13. How does the IRB need to be notified of visit changes?

Visit changes must be made in a way that protects the safety and well-being of subjects, and therefore such changes would be considered [minor deviations](#), which must be summarized at the time of continuing review or status check-in. The IRB considers that changes made in response to COVID-19 disruptions are NOT [major deviations](#), even though there could potentially be significant damage to the overall completeness, accuracy and/or reliability of the data collected for the study. Some examples of visit changes that would be considered minor deviations are omitting visit procedures that cannot be done remotely, canceling visits if doing so would not deprive benefit or impact safety, and adding the use of new remote/virtual methods for subject interaction, provided these methods comply with institutional policy for privacy and confidentiality protections.

The IRB has posted a customizable template for recording minor deviations resulting from the pause in research due to COVID-19. To download the template, click here:

<http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-Minor-Deviation-Log-Template.docx>

If a circumstance does arise with the potential to harm a subject (for example, a crucial in-person treatment or safety visit is impossible), the study team's focus should be on ways to mitigate the potential harm. After this occurs, the IRB should be notified by a Reportable Events and New Information (RENI) submission.

Please note that sponsors may have additional requirements for documenting any missed or altered visits. See the recent [FDA Guidance](#).

14. How does the IRB need to be notified of other protocol changes? (UPDATED 3/30/20)

Other modifications to the approved protocol, such as adding new remote consent processes (see #23 below) and/or requesting changes to HIPAA determinations, must be submitted using a Change Request and Amendment form and must receive IRB approval prior to implementation, unless the modification is done to prevent apparent immediate harm to the subject, in which case the IRB should be notified by a Reportable Events and New Information (RENI) submission. The IRB has added a new question to the Change Request and Amendments form to be able to identify amendments that are being submitted solely for changes due to COVID-19.

"COVID-19: Is this form being submitted ONLY to make changes that are directly related to compliance with the COVID-19 policies and restrictions on research?"

If the only changes in the amendment are due to COVID-19, please check Yes to this question. This will help the IRB stratify amendments related to COVID-19 versus those that involve other types of changes.

Please note that modifications to research given an exempt determination by the IRB do not need to be reported to the IRB unless they change the exempt determination.

15. Who else needs to be notified of the pause?

Studies with another IRB of record (ceded studies) should contact that IRB to let them know about the pause and determine any additional reporting requirements.

Funded studies should contact the Clinical Trial Office (CTO@bmc.org), BMC Research Operations (Research.Finance@bmc.org), or BU Sponsored Programs (ospera@bu.edu) to coordinate any necessary communication to sponsors.

BMC Research Operations has provided the following template which can be used for BMC-managed studies to notify sponsors, funding sources, and/or external IRBs of the pause in research activities:

<http://www.bumc.bu.edu/irb/files/2020/03/COVID-19-sponsor-funding-source-letter-template.docx>

16. Can recruitment activities continue? (EDITED 3/24/20)

Potential subjects may be contacted by mail, email, or phone to determine interest and eligibility. Most recruitment activities involving face-to-face interactions with potential subjects are NOT allowed. The only exception is recruitment for studies with the potential for direct benefit, that is, benefits that are not available through standard of care. For studies that do not have the potential for direct benefit, the potential subjects should be told during the recruitment process that their enrollment could be months away. This additional messaging does NOT need prior IRB approval.

17. What other restrictions have BU and BMC placed on research? (UPDATED 3/24/20)

Principal Investigators must prepare for the potential cessation of in-person on-campus research while managing essential equipment (e.g., refrigerators and freezers). Plans are due on Wednesday, March 25, 2020

Please use the following links for the most up-to-date information:

BU: <https://www.bu.edu/covid-19-information/>, including this link to the March 21 message concerning the potential cessation of research activities:

<https://www.bu.edu/researchsupport/2020/03/21/memo-preparation-for-potential-cessation-of-in-person-on-campus-research/>

BMC: <https://www.bmc.org/covid-19>, including links at the bottom of the page under "Research Related."

18. How will study participants receive investigational drugs?

At this time, the Investigational Pharmacy Service (IPS) is staffed and continues to provide services. If the decision and accommodations have been made to bring a subject in for an in-

person visit, IPS will provide the study medication and coordinate with the Study Coordinator to have medication picked up or delivered to the treatment area. If an in-person visit is not possible, the PI or Study Coordinator should contact the sponsor to determine if alternate options may be available. This will need to be evaluated on a case by case basis. Some sponsors/protocols/IRBs will allow for medications to be administered in alternate treatment centers or in the subject's home by the subject/caregiver or a nursing service.

Depending on the medication itself (controlled substance, drugs requiring temperature monitoring, drugs requiring immediate use once mixed, etc.), IPS may be able to coordinate delivery of the medication to the subject's home (i.e. courier, FedEx, UPS, USPS, etc.). The sponsor/CRO would be the best source to provide guidelines regarding how to handle the medication, if not already listed in the protocol or pharmacy manual. The sponsor/CRO would need to indicate how they may want in-transit temperature monitoring data to be collected, chain of custody, and/or acknowledgement of receipt documented. This will need to all be spelled out as a single event Note To File or an amendment to the Pharmacy Manual for the duration of the study. The sponsor/CRO should instruct the PI/SC what the plan is regarding what the subject should do with unused study drug. If additional packaging supplies are required, i.e. temperature monitoring devices or packaging materials, the sponsor/CRO is expected to supply them or specify what they are authorizing the site to purchase. Sponsor/CRO should indicate what type of delivery services are authorized and how they are to be billed.

IPS pharmacists will be available to the PI/SC to ensure that all the investigational dispensing issues have been asked and answered. IPS phone 617-638-6774 p 2809.

19. How can privacy be protected in communications? (UPDATED 3/30/20)

The best methods for communication are phone, BMC Zoom, BU Zoom Meetings for HIPAA, and BU Teams. Please also consider using Epic's patient portal, My Chart, for communication if the subject uses it. For BMC email, type "secure" in the subject line, which creates a secure messaging system. For BU research, you should use the [BU SecureMail email service](#) (free to use) unless the patient or research subject has agreed - ideally in writing - to use non-secure communications via email or text.

Study staff who are using their personal phones may wish to block their number from appearing as the incoming number on the subject's phone by pressing *67 prior to dialing, or by using [Doximity Dialer](#).

20. Can staff take physical/paper records home? (NEW 3/24/20)

No. The best way to access study subject information while working remotely is scanning or copying electronic research data to a securely protected platform (for BMC, [Box.com](#); for BU, various [cloud services](#)) or a shared file area behind the BMC/BU firewall, such as a Department "G: Drive." Password protection, encrypted equipment, and automatic logoff when accessing research data are required. Please contact Michelle Irick, Senior Research Compliance Manager, at Michelle.Irick@bmc.org for concerns or additional information.

21. How can study materials be shipped to subjects? (NEW 3/24/20)

Study staff should set-up a FedEx account to deliver study-related IRB approved materials that

cannot be emailed (see #19 above). BU Research Administration or BMC Research Operations at RIS@bmc.org can assist with setting up these accounts.

22. Who can answer questions about budget issues? (NEW 3/24/20)

Please contact your [BU Research Administrator](#) or [BMC Research Operations](#) for help with questions about amending the study budget for unforeseen COVID-19 related costs such as FedEx charges or study cell phones, staff salaries, etc.

23. Are there special considerations for COVID-19 research? (UPDATED 4/9/20)

The review of work relating to COVID-19 will be done in parallel by the multiple responsible offices (IRB, grants, Clinical Trial Office, IBC, etc.). Two new committees have been set up specifically to review research involving interaction with inpatient COVID-19 subjects:

Scientific Review: BMC has established a COVID-19 research scientific review committee, chaired by Benjamin Linas, MD, MPH, to review and prioritize proposals for COVID-19 research at BMC. PIs of studies involving interaction with inpatients should send a synopsis of their study to Johanna.chesley@bmc.org and Minhao.yin@bmc.org, including a supporting bibliography, that is sufficiently detailed that the committee can judge the scientific merit of the idea in comparison with other proposal treatment trials. In return, they will send some forms for the PI to fill out to make the formal request of the scientific review committee.

Implementation Review: BMC has also established an implementation committee both to assist in designing and coordinating inpatient studies to minimize the burden on PPE and clinical care and to evaluate the feasibility of the study once submitted. PIs should contact John Ennever (ennever@bu.edu) to discuss expectations for recruitment, consent and coordination with clinical care. In particular, enrollment of COVID-19 subjects should use a remote consent process, involving a witness who signs at the direction of the subject or LAR. The IRB has a customized signature page for remote consent.

For all COVID-19 studies, that both do and do not involve interaction with inpatients, please contact the IRB as soon as possible to discuss the timeline for the IRB submission at medirb@bu.edu.

24. Where can funding opportunities related to COVID-19 be found?

- NIH Guide for Grants and Contracts - search results for "COVID-19"
- NSF - Dear Colleague Letter: Provisioning Advanced Cyberinfrastructure to Further Research on the Coronavirus Disease 2019 (COVID-19) - posted 3/5/2020:
<https://www.nsf.gov/pubs/2020/nsf20055/nsf20055.jsp>

25. What guidance is available for conducting COVID-19 research using an emerging pathogen, such as SARS CoV2?

Researchers interested in conducting research with emerging pathogens such as SARS CoV2, should contact the Institutional Biosafety Committee:

<https://www.bu.edu/researchsupport/compliance/ibc/#contacts-tab>

26. What considerations are involved in receiving and/or sending materials (i.e. plasma, virus, pathogens, etc.) relating to COVID-19 from or to another organization/collaborator?

For Boston Medical Center:

- Please contact DUA.MTARequest@bmc.org for assistance.
- All requests should include 'COVID-19 for coronavirus' in the subject line.
- When receiving material: The organization/collaborator providing material to BMC usually provides a Material Transfer Agreement (MTA). Please request a template from the provider organization/collaborator and forward it to DUA.MTARequest@bmc.org for legal review. In the event the provider prefers to use a MTA template from BMC, the research attorneys can generate the document.
- When sending material: The Grants & Contracts office via DUA.MTARequest@bmc.org will prepare and send a draft MTA to the organization /collaborator for review.
- For requests for specimens from the Department of Pathology and Laboratory Medicine, see link here: <http://www.bumc.bu.edu/busm-pathology/covid-19-faqs/>

For Boston University Medical Campus:

- Please submit an online Material Transfer Agreement (MTA) Request:
 - Incoming MTA's: <https://www.bu.edu/researchsupport/forms-policies/material-transfer-agreement-mta-request-incoming-mtas/>
 - Outgoing MTA's: <https://www.bu.edu/researchsupport/forms-policies/material-transfer-agreement-mta-request/>
- BU researchers seeking to receive or share a limited data set or a data set with PHI should complete and submit the online data use agreement request form found here: <https://www.bu.edu/researchsupport/forms-policies/data-use-agreement-form/>

27. What updates are required to ClinicalTrials.gov records? (NEW 3/25/20)

Certain studies listed on ClinicalTrials.gov that have paused recruitment should have their recruitment status changed from Recruiting or Enrolling by Invitation to Suspended, within 30 days of the change. The ClinicalTrials.gov administrator, Karla Damus (damusk@bu.edu) is in the process of contacting study teams where this change may be required and will offer assistance, or will make the status change, as requested by the study team. In addition, it is likely that the Primary Completion Date and the Study Completion Date will have to be extended for paused studies. Again, Karla will be contacting and assisting study teams as their Primary Completion Date or Study Completion Date approaches. Please contact Karla with questions or for additional information.

28. What is the effect of the pause in research on Massachusetts Controlled Substances Registration (MCSR) Research Licenses? (NEW 3/25/20)

The requirement that PIs who are conducting any study that has an IND must obtain an individual MCSR research license prior to administering any drug *has not changed*. We recommend that PIs keep to the pre-pause schedule for applying for their MCSR research licenses, even if all of their studies are paused, to avoid any delays in restarting once the pause is

lifted. Please contact the MCSR research license administrator, Karla Damus (damusk@bu.edu) with any questions about the research license schedule or requirements.

29. Can study monitors get remove access to EPIC? (NEW 4/9/20)

Monitors can get “over-the-shoulder” access to EPIC by participating in a secure remote meeting (see #19. Above) with study staff in which a study staff member accesses EPIC and shares their screen with the monitor.